

Serial No.: 10/606,909

Confirmation No.: 5688

Filed: June 26, 2003

For: METHOD AND APPARATUS FOR PROVIDING INTRA-PERICARDIAL ACCESS

Remarks

The Office Action mailed January 26, 2010 has been received and reviewed. In this amendment and response, claim 39 has been amended. Therefore, the pending claims are claims 39-41 and 43-45. However, claim 40 has been withdrawn from consideration by the Examiner. As such, the remarks provided herein are made with regard to claims 39, 41, and 43-45. Reconsideration and withdrawal of the rejections are respectfully requested in view of the amendment and remarks provided herein.

Claim Amendment

Claim 39 has been amended to clarify the amendment made in response to the previous office action, wherein it was recited that the elongated inner tubular member was coaxially nested within the lumen of the outer tubular body “from at least the proximal end of the outer tubular body to the distal end thereof” to longitudinally move and rotate therein. It is believed that the Examiner misinterpreted this previously amended limitation so as not to require the lumen of the outer tubular body to be open on both ends such that the elongated inner tubular member is coaxially nested within the lumen of the outer tubular body from at least the proximal end of the outer tubular body to the distal end thereof, and such that the elongated inner tubular member can longitudinally move and rotate within the outer tubular body.

As such, and without any further narrowing of claim 39, Applicants have amended the claim to clarify that the lumen of the outer tubular body is open on both the proximal and distal ends such that the elongated inner tubular member coaxially nested within the lumen of the outer tubular body can longitudinally move and rotate within the outer tubular body. To provide such clarification, claim 39 has been amended to recite that “the elongated inner tubular member coaxially nested within the lumen of the elongated outer tubular body extends in a proximal direction beyond the proximal end of the elongated outer tubular body and extends in a distal direction beyond the distal end of the elongated outer tubular body.” It is believed that the scope of the claim is intended to be the same after the amendment as it was before the amendment.

Such an amendment of the claim is supported by at least the Figures 9-11 as well as the description of such Figures in the specification.

The 35 U.S.C. §103 Rejection

The Examiner rejected claims 39, 41, and 43-45 under 35 U.S.C. §103(a) as being unpatentable over Okada et al. (U.S. Patent No. 5,672,158) in view of Fandetti et al. (U.S. Patent No. 3,645,562) and in further view of Hamilton et al. (U.S. Patent No. 1,738,996). Applicants respectfully traverse the Examiner's rejections.

To establish a *prima facie* case of obviousness, there must be a finding that the prior art included each element claimed, although not in a single prior art reference. *See* M.P.E.P. § 2143.

Okada et al., Fandetti et al., and Hamilton et al. do not describe, teach or suggest all the elements of claim 39.

Applicants have previously argued that claim 39 specifies an ***elongated*** outer tubular body having a lumen and an elongated inner tubular member nested within the lumen of the ***elongated*** outer tubular body to longitudinally move and rotate therein and that Okada et al. does not describe such structure. Further, per the response to the last office action and per the clarification of claim 39 herein, Applicants also argue that Okada et al. does not describe that the elongated inner tubular member coaxially nested within the lumen of the elongated outer tubular body extends in a proximal direction beyond the proximal end of the elongated outer tubular body and extends in a distal direction beyond the distal end of the elongated outer tubular body. In other words, the ends of the elongated outer tubular body are open such that the elongated inner tubular member extends through such proximal and distal ends.

The Examiner alleges that Akada et al. shows in Fig. 9 (shown below) an elongated outer tubular body (flange 37) having a lumen extending from a proximal end to a distal end with an inner surface provided with an inwardly directed projection; and an elongated inner tubular member 32 coaxially nested within the lumen of the outer tubular body (the flange 37) and having an outer surface provided with outwardly directed projections.

Serial No.: 10/606,909

Confirmation No.: 5688

Filed: June 26, 2003

For: METHOD AND APPARATUS FOR PROVIDING INTRA-PERICARDIAL ACCESS

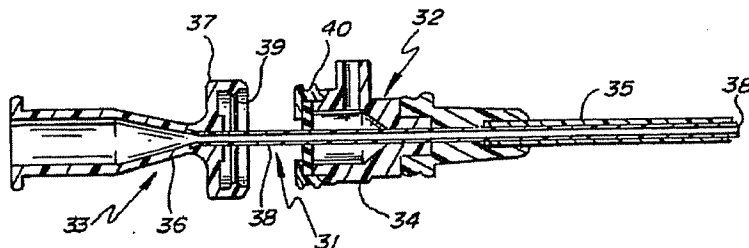


Fig. 9.

However, as is evident from Figure 9, the sheath section 32 is not an “inner elongated tubular member” coaxially nested within the lumen of an “elongated outer tubular body” (i.e., alleged by the Examiner to now be the flange 37) so as to longitudinally move and rotate therein. The Examiner continues to allege that the “elongated” term does not imply a specific length for the structure and that the amendments to the claim made in response to the last office action do not further define the length of the structures (see Response to Arguments, page 7, current Office Action).

Even though Applicants, in response to the previous Office Action, amended claim 39 with language believed to be like that suggested by the Examiner (e.g., that “the inner tubular member is nested within the entire length of the lumen of the elongated outer tubular member”), the Examiner continues to reject the claim for similar reasons. It is clear that the sheath section 32 is not coaxially nested within the opening of the flange 37 from the proximal end of the flange 37 to the distal end thereof, as the opening in the flange 37 alleged by the Examiner to be equatable to the lumen of the outer tubular body is completely closed on the proximal end.

However, to move this case to issuance, claim 39 has again been amended to clarify the “elongation” terminology and the nesting of the inner tubular member in the lumen of the outer tubular body (e.g., precluding an interpretation set forth by the Examiner even when equating the flange 37 to the elongated outer tubular body). For example, claim 39 now recites that “the elongated inner tubular member coaxially nested within the lumen of the elongated outer tubular

Serial No.: 10/606,909

Confirmation No.: 5688

Filed: June 26, 2003

For: METHOD AND APPARATUS FOR PROVIDING INTRA-PERICARDIAL ACCESS

body extends in a proximal direction beyond the proximal end of the elongated outer tubular body and extends in a distal direction beyond the distal end of the elongated outer tubular body.”

In view of such clarification in amended claim 39, Okada et al. cannot possibly be read so broadly as to allege that it describes, teaches or suggests the structure of the elongated inner tubular member and its nested position within the lumen of the elongated outer tubular body. As such, the structural arrangement recited in amended claim 39 is not shown by Okada et al.

Further, for example, Okada et al. does not describe that the elongated inner tubular member be nested within the lumen of the elongated outer tubular body to longitudinally move and rotate therein as is also recited in claim 39. By identifying the flange 37 as the outer tubular body and the sheath section 32 as the inner tubular member, the limitation that the elongated inner tubular member be nested within the lumen of the elongated outer tubular body to longitudinally move and rotate therein as recited in claim 39 is necessarily absent from Okada et al. Rather, once sheath hub 34 of sheath section 32 with groove 40 is snapped into place within flange 37 of dilator hub 36 of the dilator section 33, there is no longitudinal or rotational movement of sheath hub 34 within flange 37. Moreover, Okada describes this in detail and without question at column 4, lines 46-65. In fact, the structure of Okada et al. (e.g., the flange 37 and groove 40 are expressly designed to restrict relative rotation or axial movement). See col. 4, lines 54-55 (“ . . . it does not happen that the dilator section 33 and the sheath section 32 rotate relatively or are displaced in the axial direction . . .”).

Fandetti et al. and Hamilton et al. are only used by the Examiner to show locking mechanisms and/or frustoconical flanges, and they do not cure the deficiencies of Okada et al. Therefore, the cited references do not teach all the limitations of claim 39 and for at least this reason alone, claim 39 is not obvious in view of the cited references.

As claims 41 and 43-45 depend on claim 39, either directly or indirectly, they include all the limitations of claim 39. As such, for the same reasons as set forth herein with respect to

Serial No.: 10/606,909

Confirmation No.: 5688

Filed: June 26, 2003

For: METHOD AND APPARATUS FOR PROVIDING INTRA-PERICARDIAL ACCESS

claim 39 (as well as by reason of their own limitations), dependent claims 41 and 43-45 are also not obvious over the references cited.

It is respectfully requested that the rejections of claims 39, 41, and 43-45 be withdrawn.

Summary

It is respectfully submitted that the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

Mueiting, Raasch & Gebhardt, P.A.

P.O. Box 581336

Minneapolis, MN 55458-1336

Phone: (612) 305-1220

Facsimile: (612) 305-1228

Customer Number 26813

25 March 2010

Date

By: 

Mark J. Gebhardt

Reg. No. 35,518

Direct Dial (612) 305-1216

CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 25th day of March, 2010.

By: 

Name: Deb Schurmann
